

PATENT

Atty. Docket No. 1400-004

JE903 U.S. PRO

10/053505



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

ROBERTS, William J.

 Entitled: "BIOAVAILABLE PRODRUGS OF  
ANDROGENIC STEROIDS AND RELATED  
METHOD"

Serial No. Not Yet Assigned

Filed: January 16, 2002

# 2

BOX APPLICATION

 Assistant Commissioner  
for Patents

 U.S. Patent and Trademark Office  
Washington, D.C. 20231

**PETITION TO MAKE SPECIAL UNDER**  
**37 C.F.R. § 1.102 AND MPEP 708.02**

Dear Sir:

Applicant hereby petitions to make special the application filed herewith, on the ground of actual infringement of at least some of the claims of the application. Also filed herewith are (a) a petition fee; (b) a Declaration of Tim Allyn Patterson in Support of Petition under 37 C.F.R. § 102 and MPEP 708.02 (hereinafter "Patterson Decl."); and (c) Declaration of Steven T. Sullivan in Support of Petition under 37 C.F.R. § 102 and MPEP 708.02 (hereinafter "Sullivan Decl.).

There is currently an infringing product being produced in China specifically for importation into the United States for resale that gives rise to this infringement and grounds for this Petition to Make Special. On information and belief, the infringing device or product is being made and exported into the United States by Taizhou Xingye Chemical Factory as 4-androstenediol ethyl carbonate. See Patterson Decl. at ¶ 2-3. It includes a diester component as well as a monoester component. (Id.)

Mr. Patterson and Mr. Sullivan have made a comparison of the alleged infringing product with the claims of the application. In their opinion, at least some of the claims of the application are unquestionably infringed. See Patterson Decl. at ¶ 5 and Sullivan Decl. at ¶ 5.

A search relating to the subject matter of this invention has been conducted, and the results of that search are being filed concurrently with the application papers and this Petition in an Information Disclosure Statement. Sullivan Decl.

Based on the information known to Applicant at this time, including the documents submitted in the Information Disclosure Statement, the invention as recited in at least claims 1-6 and 21-26 are novel and are not obvious in view of this art.

The product in question, based upon the document attached to the Sullivan and Patterson Declarations, clearly infringes claims 1-6, for example, in that they comprise a substrate comprising androst-4-ene-3 $\alpha$ ,17 $\beta$ -diol, androst-4-ene-3 $\beta$ ,17 $\beta$ -diol, and mixtures thereof. Note that it includes 4-androstenediol, which is believed

to be alternate nomenclature for androst-4-ene-3,17 $\beta$ -diol. Claim 1 also recites that the compound comprises a promoiety comprising an alkylcarbonate ester. Claim 3 recites that the wherein the compound comprises androst-4-ene-3,17 $\beta$ -diol 17 $\beta$ -alkylcarbonate, and claim 4 recites that the compound comprises androst-4-ene-3,17 $\beta$ -diol 17 $\beta$ -ethylcarbonate. The exhibit indicates that the accused product includes a monoester 4-androstenediol ethyl carbonate component, which clearly corresponds to the compound of claims 1 and 3-4.

Claim 5 recites that the compound comprises androst-4-ene-3,17 $\beta$ -diol 3,17 $\beta$ -di(alkylcarbonate), and claim 6 recites that it comprises androst-4-ene-3,17 $\beta$ -diol 3,17 $\beta$ -di(ethylcarbonate). The exhibit indicates that the accused product also includes a 4-androstenediol ethyl carbonate diester component which clearly infringes these claims.

Claim 2 recites that the alkylcarbonate ester has an alkyl chain length of less than 12. Both of the aforementioned components are identified in the exhibit as comprising ethyl carbonates, clearly involving an alkyl chain length of less than 12, and therefore indicating that claim 2 is infringed as well.

Method claims 21-26 recite that a compound as generally described above is administered to a subject. The correspondence of the accused product to the compound of claims 1-6 is clear, as explained above. It is clear from the nature of these products and from the manufacturer that these products are intended to be administered to subjects. Accordingly, their importation into the United States,

sale, and use in this country comprise contributory infringement of method claims 21-26 and inducement to infringe them.

Applicant accordingly requests that this application be given special status, and that it be prosecuted on a greatly expedited basis so that this infringement can be stopped. Substantial and potentially irreparable harm will result if this infringement is not abated at the earliest possible time.

Applicant stands ready to assist in advancing the prosecution of this application.

A Petition fee is being submitted herewith to cover the fee for this Petition. If this Petition fee is deficient in any way, please charge the deficiency or other fee to our Deposit Account No. 501324.

An early and favorable decision on this Petition is respectfully requested.

Respectfully submitted,

Dated: January 16, 2002

Sullivan Law Group

By: \_\_\_\_\_



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## CERTIFICATE OF EXPRESS MAIL

Express Mail Mailing Label No. EV054088650US

Date of Deposit: January 16, 2002

I hereby certify that this Petition and associated fee are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Box Patent Application, Assistant Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202-0327.

Anne K Hoole